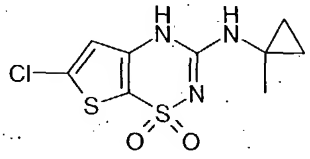
CLAIMS

What is claimed is:

1. A polymorphic/pseudopolymorphic form or a mixture thereof of 6-chloro-3-(1-methylcyclopropyl)amino-4H-thieno[3,2-e]-1,2,4-thiadiazine 1,1-dioxide of formula (I)



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or a pharmaceutically acceptable solvate thereof.

2. A polymorphic/pseudopolymorphic form according to claim 1 obtained from the solvents acetic acid, acetone, anisole, 1-butanol, 2-butanol, butylacetate, butylmethylether, cumene, DMSO (dimethylsulfoxide), ethanol, 1- propanol, 2-propanol, ethylacetate, ethylether, ethylformate, formic acid, heptane, iso-butylacetate, iso-propylacetate, methanol, methylacetate, 3-methyl-1-butanol, methylethyl ketone, methyl iso-butyl ketone, 2-methyl-1-propanol, pentane, 1-pentanol, propylacetate, or water or any combination thereof.

3. A polymorphic form (A) according to claim 1, having the characteristics as described in Example 2.

4. A polymorphic form (B) according to claim 1, having the characteristics as described in Example 3.

5. A pseudopolymorphic form (C*j*), *j* = 1, 2, 3, 4, 5, 6, 7, 8 or 9, according to claim 1, having the characteristics as described in Examples 4, 5, 6, 7, 8, 9, 10, 11 and 12.

6. A polymorphic form (D) according to claim 1, having the characteristics as described in Example 13.

7. A mixture of polymorphic forms according to claim 1, comprising polymorphic form (A) and polymorphic form (B), having the characteristics as described in Example 14.

8. A mixture of polymorphic/pseudopolymorphic forms according to claim 1, comprising polymorphic form (B) and one of the pseudopolymorphic forms (C*j*), *j* = 1, 2, 3, 4, 5, 6, 7, 8 or 9, having the characteristic as described in Example 15.

9. A pharmaceutical composition comprising, as an active ingredient, a polymorphic/pseudopolymorphic form or a mixture thereof according to claim 1, together with one or more pharmaceutically acceptable carriers or excipients.

10. A pharmaceutical composition comprising, as an active ingredient, a polymorphic/pseudopolymorphic form or a mixture thereof according to claim 2, together with one or more pharmaceutically acceptable carriers or excipients.

11. A pharmaceutical composition comprising, as an active ingredient, the polymorphic form (A) according to claim 3, together with one or more pharmaceutically acceptable carriers or excipients.

12. A pharmaceutical composition comprising, as an active ingredient, the polymorphic form (B) according to claim 4, together with one or more pharmaceutically acceptable carriers or excipients.

13. A pharmaceutical composition comprising, as an active ingredient, the pseudopolymorphic form (Cj), j = 1, 2, 3, 4, 5, 6, 7, 8 or 9, according to claim 5, together with one or more pharmaceutically acceptable carriers or excipients.

14. A pharmaceutical composition comprising, as an active ingredient, the polymorphic form (D) according to claim 6, together with one or more pharmaceutically acceptable carriers or excipients.

15. A pharmaceutical composition comprising, as an active ingredient, the mixture of polymorphic form (A) and polymorphic form (B) according to claim 7, together with one or more pharmaceutically acceptable carriers or excipients.

16. A pharmaceutical composition comprising, as an active ingredient, the mixture of polymorphic form (B) and one of the pseudopolymorphic form (Cj), j = 1, 2, 3, 4, 5, 6, 7, 8 or 9,

according to claim 8 together with one or more pharmaceutically acceptable carriers or excipients.

17. A pharmaceutical composition according to claim 9 in unit dosage form, comprising from about 0.05 mg to about 1000 mg, from about 0.1 to about 500 mg or from about 0.5 mg to about 200 mg per day of a polymorphic/pseudopolymorphic form or mixture thereof.

18. A pharmaceutical composition for the treatment or prevention of diseases of the endocrinological system such as treatment of hyperinsulinaemia, treatment or prevention of Type-2 diabetes, prevention of Type-2 diabetes in prior GDM, prevention and intervention of Type-1 diabetes, prevention or slowing of progression of impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), gestational diabetes mellitus (GDM) or obesity, the composition comprising, as an active ingredient, a polymorphic/pseudopolymorphic form or mixture thereof according to claim 1, together with one or more pharmaceutically acceptable carriers or excipients.

19. A pharmaceutical composition for the treatment or prevention of diseases of the endocrinological system such as treatment of hyperinsulinaemia, treatment or prevention of Type-2 diabetes, prevention of Type-2 diabetes in prior GDM, prevention and intervention of Type-1 diabetes, prevention or slowing of progression of impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), gestational diabetes mellitus (GDM) or obesity, the composition comprising, as an active ingredient, the polymorphic form (A) according to claim 3, together with one or more pharmaceutically acceptable carriers or excipients.

20. A pharmaceutical composition for the treatment or prevention of diseases of the endocrinological system such as treatment of hyperinsulinaemia, treatment or prevention of Type-2 diabetes, prevention of Type-2 diabetes in prior GDM, prevention and intervention of Type-1 diabetes, prevention or slowing of progression of impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), gestational diabetes mellitus (GDM) or obesity, the composition comprising, as an active ingredient, the polymorphic form (B) according to claim 4, together with one or more pharmaceutically acceptable carriers or excipients.

21. A pharmaceutical composition for the treatment or prevention of diseases of the endocrinological system such as treatment of hyperinsulinaemia, treatment or prevention of Type-2 diabetes, prevention of Type-2 diabetes in prior GDM, prevention and intervention of

Type-1 diabetes, prevention or slowing of progression of impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), gestational diabetes mellitus (GDM) or obesity, the composition comprising, as an active ingredient, the pseudopolymorphic form (C*j*), *j* = 1, 2, 3, 4, 5, 6, 7, 8 or 9, according to claim 5, together with one or more pharmaceutically acceptable carriers or excipients.

22. A pharmaceutical composition for the treatment or prevention of diseases of the endocrinological system such as treatment of hyperinsulinaemia, treatment or prevention of Type-2 diabetes, prevention of Type-2 diabetes in prior GDM, prevention and intervention of Type-1 diabetes, prevention or slowing of progression of impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), gestational diabetes mellitus (GDM) or obesity, the composition comprising, as an active ingredient, the polymorphic form (D) according to claim 6, together with one or more pharmaceutically acceptable carriers or excipients.

23. A pharmaceutical composition for the treatment or prevention of diseases of the endocrinological system such as treatment of hyperinsulinaemia, treatment or prevention of Type-2 diabetes, prevention of Type-2 diabetes in prior GDM, prevention and intervention of Type-1 diabetes, prevention or slowing of progression of impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), gestational diabetes mellitus (GDM) or obesity, the composition comprising, as an active ingredient, the mixture of polymorphic form (A) and (B) according to claim 7, together with one or more pharmaceutically acceptable carriers or excipients.

24. A pharmaceutical composition for the treatment or prevention of diseases of the endocrinological system such as treatment of hyperinsulinaemia, treatment or prevention of Type-2 diabetes, prevention of Type-2 diabetes in prior GDM, prevention and intervention of Type-1 diabetes, prevention or slowing of progression of impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), gestational diabetes mellitus (GDM) or obesity, the composition comprising, as an active ingredient, the mixture of polymorphic form (B) and pseudopolymorphic form (C*j*), *j* = 1, 2, 3, 4, 5, 6, 7, 8 or 9, according to claim 8, together with one or more pharmaceutically acceptable carriers or excipients.

25. A method for the treatment or prevention of diseases of the endocrinological system such as treatment of hyperinsulinaemia, treatment or prevention of Type-2 diabetes, prevention of Type-2 diabetes in prior GDM, prevention and intervention of Type-1 diabetes,

prevention or slowing of progression of impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), gestational diabetes mellitus (GDM) or obesity, the method comprising administering to a subject in need thereof an effective amount of a polymorphic/pseudo-polymorphic form or mixture thereof according to claim 1, or a pharmaceutical composition comprising the same.

26. A method for the treatment or prevention of diseases of the endocrinological system such as treatment of hyperinsulinaemia, treatment or prevention of Type-2 diabetes, prevention of Type-2 diabetes in prior GDM, prevention and intervention of Type-1 diabetes, prevention or slowing of progression of impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), gestational diabetes mellitus (GDM) or obesity, the method comprising administering to a subject in need thereof an effective amount of the polymorphic form (A) according to claim 3, or a pharmaceutical composition comprising the same.

27. A method for the treatment or prevention of diseases of the endocrinological system such as treatment of hyperinsulinaemia, treatment or prevention of Type-2 diabetes, prevention of Type-2 diabetes in prior GDM, prevention and intervention of Type-1 diabetes, prevention or slowing of progression of impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), gestational diabetes mellitus (GDM) or obesity, the method comprising administering to a subject in need thereof an effective amount of the polymorphic form (B) according to claim 4, or a pharmaceutical composition comprising the same.

28. A method for the treatment or prevention of diseases of the endocrinological system such as treatment of hyperinsulinaemia, treatment or prevention of Type-2 diabetes, prevention of Type-2 diabetes in prior GDM, prevention and intervention of Type-1 diabetes, prevention or slowing of progression of impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), gestational diabetes mellitus (GDM) or obesity, the method comprising administering to a subject in need thereof an effective amount of the pseudopolymorphic form (Cj), j = 1, 2, 3, 4, 5, 6, 7, 8 or 9, according to claim 5, or a pharmaceutical composition comprising the same.

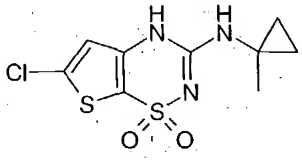
29. A method for the treatment or prevention of diseases of the endocrinological system such as treatment of hyperinsulinaemia, treatment or prevention of Type-2 diabetes, prevention of Type-2 diabetes in prior GDM, prevention and intervention of Type-1 diabetes, prevention or slowing of progression of impaired fasting glucose (IFG) and impaired glucose

tolerance (IGT), gestational diabetes mellitus (GDM) or obesity, the method comprising administering to a subject in need thereof an effective amount of the polymorphic form (D) according to claim 6, or a pharmaceutical composition comprising the same.

30. A method for the treatment or prevention of diseases of the endocrinological system such as treatment of hyperinsulinaemia, treatment or prevention of Type-2 diabetes, prevention of Type-2 diabetes in prior GDM, prevention and intervention of Type-1 diabetes, prevention or slowing of progression of impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), gestational diabetes mellitus (GDM) or obesity, the method comprising administering to a subject in need thereof an effective amount of the mixture of polymorphic form (A) and (B) according to claim 7, or a pharmaceutical composition comprising the same.

31. A method for the treatment or prevention of diseases of the endocrinological system such as treatment of hyperinsulinaemia, treatment or prevention of Type-2 diabetes, prevention of Type-2 diabetes in prior GDM, prevention and intervention of Type-1 diabetes, prevention or slowing of progression of impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), gestational diabetes mellitus (GDM) or obesity, the method comprising administering to a subject in need thereof an effective amount of the mixture of polymorphic form (B) and pseudopolymorphic form (C*j*), *j* = 1, 2, 3, 4, 5, 6, 7, 8 or 9, according to claim 8, or a pharmaceutical composition comprising the same.

32. A process for the preparation of polymorphic/pseudopolymorphic forms or mixtures thereof of 6-chloro-3-(1-methylcyclopropyl)amino-4H-thieno[3,2-e]-1,2,4-thiadiazine 1,1-dioxide of formula (I)



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which process comprises:

a) suspending or dissolving 6-chloro-3-(1-methylcyclopropyl)amino-4H-thieno[3,2-e]-1,2,4-thiadiazine 1,1-dioxide in an appropriate solvent or a mixtures of solvents,

b) optionally heating the mixture to 60-120°C depending on the boiling point of the appropriate solvent or solvent mixture so that the solution becomes clear, and filtering the clear solution,

c) optionally adding a co solvent at 60-120°C,

d) optionally distilling off solvent,

e) slowly cooling the solution to 0-50°C, or adding the solution to a third solvent or mixture of solvents, or adding solvent or a mixture of solvents to the solution or combinations thereof whereby crystals are formed,

g) filtrating the resulting suspension,

h) washing the filter cake with an appropriate solvent or mixture of solvents and drying the filter cake to constant weight.